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09/012,369	01/23/1998	BENJAMIN LEWIS MARGOLIS	231/198	2028

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/012,369

Applicant(s)

MARGOLIS ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 26-32 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-32 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 24.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 29.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. The finality of the rejection of the last Office action is withdrawn in view of new grounds of rejection.

2. The amendment filed Feb. 3, 2003 is acknowledged. The amendment has been entered; claims 26 and 31 were amended.

Claims 26-32 and 35 are pending and examined on the merits.

3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

#### ***Claim Rejections Withdrawn:***

4. The rejection of pending claims 26-32 and 35 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn upon further consideration of the phrases “therapeutically effective amount” and “agent”. The meaning of these terms is clear, even if the scope of these terms is broad.

5. The rejection of claims 26-32, and 35 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, because of the introduction of new matter, is withdrawn in view of the amendment.

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***Claim Rejections Maintained:***

6. The rejection of pending claims 26-32 and 35 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for the reasons of record.

Applicant's arguments have been considered, but are unpersuasive. The breadth of the claims is not commensurate in scope with the breadth of the disclosure. The rejection is maintained because the lack of correlation of scope of the claims with that of the specification, coupled with the unpredictability of protein chemistry and the lack of clear functional language (what disease is treated; which signal transduction pathways are altered) and fact that the claims do not structurally define an "APB recognition region present in a first protein".

***New Grounds of Rejection:***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 26, 31, 32 and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by Comoglio (U.S. Patent 5,912,183; issued Jun., 1999; effective filing date Jun. 27, 1994).

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Claims 26, 31, 32 and 35 are drawn to methods comprising administration to a patient an agent which decreases binding between an APB recognition region present in a first protein and an APB domain present in a second protein, where the APB domain shares at least 75 % sequence similarity or at least 80% sequence identity with the APB domain present in 46-109 of p52Shc as set forth in SEQ ID NO: 2. The first protein may be a receptor tyrosine kinase. The agent may be an organic molecule, an inorganic molecule or a polypeptide. The receptor tyrosine kinase may be an EGF receptor, Her-2 or Trk. Because the claims do not recite how the agent disrupts the binding between the two proteins, it is assumed that agent need not bind specifically to either the APB domain or to the APB recognition sequence.

Comoglio teaches peptides that inhibit the binding of receptor protein tyrosine kinases with their intracellular transducers (see claims 1 and 3; col. 41 and 42). Comoglio teaches that EGF binds to Grb2 (see col. 2, lines 25-29). Comoglio teaches methods of in vivo administration (see col. 8, lines 17-35). Thus, Comoglio teaches methods that are the same as that claimed.

8. Claims 26-32 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the specification fails to adequately describe the genus of "agents", because the specification fails to structurally representative examples of the genus.

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The description of the "term" agent is defined throughout the specification, where the specific descriptions at page 6, lines 7-9, page 10, lines 3-15, particularly lines 12-15, and page 23, line 26- page 33, line 7 amount to a general contemplation of the genus of agents by a description of general functions. The specification fails to provide representative examples in the form of specific structures. Thus, the specification fails to provide evidence that any of these structures were conceived at the time of filing.

9. Claims 27-30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 27, 29 and 32 are indefinite because the phrase "said agent" lacks antecedent basis in claim 26, which recites the phrase "therapeutic agent".

### *Conclusion*


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran  
Patent Examiner  
June 4, 2003

  
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